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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/062,299	01/31/2002	Leroy E. Hood	P-IS 5150	2563
41552	7590	12/09/2005	EXAMINER	
MCDERMOTT, WILL & EMERY 4370 LA JOLLA VILLAGE DRIVE, SUITE 700 SAN DIEGO, CA 92122			SMITH, CAROLYN L	
			ART UNIT	PAPER NUMBER
			1631	
DATE MAILED: 12/09/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/062,299

Applicant(s)

HOOD ET AL.

Examiner

Carolyn L. Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 1-21 and 36-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission, filed 9/26/05, has been entered.

Amended claims 22, 24, and 30, filed 9/26/05, are acknowledged.

Claims herein under examination are 22-35. Claims 1-21 and 36-49 remain withdrawn as being drawn to non-elected Groups.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 24-35 are rejected under 35 U.S.C. 101 because these claims are directed to non-statutory subject matter.

Claims 24-35 are directed to methods for assigning a cellular function to a component of a biological system comprising a series of mathematical steps for data manipulation, equivalent to mental processes. Applicant is reminded that mental processes are not statutory subject matter under 35 USC 101.

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As set forth in MPEP 2106.IV.B.I:

If the "acts" of a claimed process manipulate only numbers, abstract concepts or ideas, or signals representing any of the foregoing, the acts are not being applied to appropriate subject matter. *Schrader*, 22 F.3d at 294-95, 30 USPQ2d at 1458-59. Thus, a process consisting solely of mathematical operations, i.e., converting one set of numbers into another set of numbers, does not manipulate appropriate subject matter and thus cannot constitute a statutory process.

In practical terms, claims define nonstatutory processes if they:

- consist solely of mathematical operations without some claimed practical application (i.e., executing a "mathematical algorithm"); or
- simply manipulate abstract ideas, e.g., a bid (*Schrader*, 22 F.3d at 293-94, 30 USPQ2d at 1458-59) or a bubble hierarchy (*Warmerdam*, 33 F.3d at 1360, 31 USPQ2d at 1759), without some claimed practical application.

The methods of claims 24-35 are not restricted to be computer-implemented methods; however, the specification indicates that the methods are intended to be implemented by a computer. In the event that the claimed method steps are implemented by a computer, the method claims are not statutory due to a lack of physical transformation outside the computer and a practical application (as discussed below).

According to MPEP 2106.IV.B.2(b):

To be statutory, a claimed computer-related process must either: (A) result in a physical transformation outside the computer for which a practical application in the technological arts is either disclosed in the specification or would have been known to a skilled artisan, or (B) be limited to a practical application within the technological arts. See *Diamond v. Diehr*, 450 U.S. at 183-84, 209 USPQ at 6 (quoting *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1877)).

As set forth in MPEP 2106.IV.B.2(b)(i), two "safe harbors" considered to satisfy the "physical transformation outside the computer" requirement include the following:

- (1) A process is statutory if it requires physical acts to be performed outside the computer independent of and following the steps to be performed by a programmed computer, where those acts involve the manipulation of tangible physical objects and result in the object having a different physical attribute or structure. *Diamond v. Diehr*, 450 U.S. at 187, 209 USPQ at 8.
- (2) Another statutory process is one that requires the measurements of physical objects or activities to be transformed outside of the computer into computer data (*In re Gelnovatch*, 595 F.2d 32, 41 n.7, 201 USPQ 136, 145 n.7 (CCPA 1979)).

While claims 24-35 recite the determination of a multidimensional coordinate point representing a data element of a physically perturbed biochemical system, the physical perturbation is interpreted to have occurred before the determining step. No physical acts were performed in the actual method steps. Therefore, claims 24-35 do not recite any physical act considered to be a physical transformation as explained above.

As discussed in MPEP 2106.IV.B.2(b)(i):

If a claim does not clearly fall into one or both of the safe harbors, the claim may still be statutory if it is limited to a practical application in the technological arts.

As set forth in MPEP 2106.IV.B.2(b)(ii), an explanation of “practical application” as well as some examples of claimed inventions that have a practical application include the following:

A claim is limited to a practical application when the method, as claimed, produces a concrete, tangible and useful result; i.e., the method recites a step or act of producing something that is concrete, tangible and useful. See *AT&T*, 172 F.3d at 1358, 50 USPQ2d at 1452. Likewise, a machine claim is statutory when the machine, as claimed, produces a concrete, tangible and useful result (as in *State Street*, 149 F.3d at 1373, 47 USPQ2d at 1601) and/or when a specific machine is being claimed (as in *Alappat*, 33 F.3d at 1544, 31 USPQ2d at 1557 (**en banc*)). For example, a computer process that simply calculates a mathematical algorithm that models noise is nonstatutory. However, a claimed process for digitally filtering noise employing the mathematical algorithm is statutory.

The “practical application” toward which instant claims 24-35 are apparently directed is the determination of whether the multidimensional coordinate point is within or outside a reference data element region for possible assignment of a cellular function of a network. This “practical application” does not satisfy the 35 USC 101 statutory requirements, because there is no concrete, tangible, and useful result in these claims.

Because the claimed methods merely recite steps of mathematically manipulating data and fail to recite a physical transformation (as explained above) or produce a practical

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application (a concrete, tangible, and useful result), claims 24-35 do not recite statutory subject matter.

Applicants argue that claims 22, 24, and 30 have been amended to clearly specify the claimed perturbation step constitutes a physical act on a network of a biochemical system. It is agreed that amended claim 22 clearly recites a physical step. However, amended claims 24 and 30 do not include such a physical step. Instead, claims 24 and 30 determine a multidimensional coordinate point representing a data element of a physically perturbed biochemical system. This step is not a physical act performed outside a computer or a measuring of physical objects or activities (two “safe harbor” categories satisfying the physical transformation requirement for statutory subject matter), but rather a determination of a multidimensional coordinate point representing data manipulation of a data element that can be interpreted to have been previously perturbed (before the determination step). Therefore, instant claims 24 and 30 and their dependent claims are considered to be non-statutory subject matter.

Claim Rejections – 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 22-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Stoughton et al. (P/N 6,132,969).

Stoughton et al. disclose laboratory and computer methods for testing and confirming how well a network model represents a biological pathway in a biological system (abstract) wherein the biological pathway in a biological system represents a biochemical system. Stoughton et al. disclose obtaining measurements for drug and pathway responses (col. 52, lines 56-62) and perturbing and monitoring components in a network model (col. 53, lines 38-64) which represents physically perturbing a component, as stated in instant claim 22. Stoughton et al. disclose the network comprises logical operators relating to input cellular constituents (components), such as mRNA and proteins, to output classes of cellular constituents which are affected by the pathway (abstract), which represents assigning a cellular function to components (col. 10, line 61 to col. 11, line 3), as stated in instant claims 22, 24, and 30. Stoughton et al. disclose use of positionally addressable transcript microarrays which are ordered and reproducible matrices for easy comparison with each other and capable of containing single sites per specific mRNA (col. 45, lines 17-39, col. 46, lines 58-67, and col. 51, lines 39-49) and making measurements of graded drug exposure and of graded levels of modification/perturbation control parameters (col. 52, lines 1-17) wherein the microarrays inherently involve mRNA locations containing x and y dimensions (multidimensional coordinate points) for components of a physically perturbed system including n parameters (i.e. drug exposure and levels of perturbation) corresponding to the number of measured components within the biochemical system, as stated in instant claims 22, 24, and 30. Figure 9 illustrates positioning “0” state over “1” state (col. 28, lines 3-22) which represents comparison to a reference region, as stated in

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instant claims 22, 24, and 30. Stoughton et al. disclose comparing relative changes in the biological system in response to perturbations of the network (abstract and col. 8, lines 40-41 and col. 8, line 64 to col. 9, line 12). Stoughton et al. disclose comparing relative changes between two states in a biological system (col. 3, lines 15-20) including normal reference "0" and perturbed expression "1" states (col. 7, lines 50-64 and col. 8, lines 34-52), which represents comparison to a reference expression region, as stated in instant claims 22, 24, 27, 30, and 33. Stoughton et al. disclose predicting how output classes behave in response to the chosen experiments by finding measures (multidimensional coordinate points) of relative change of cellular constituents (components) and finding goodnesses of fit ("the conformity between an experimental result and theoretical expectation", according to Merriam-Webster's online dictionary) of each observed component to an output class (reference data element region) based on strongest correlations (abstract), which represent a linkage to the perturbed biochemical network. Stoughton et al. disclose analyzing a scanned image by using an image gridding program that creates a spreadsheet of the average hybridization at each wavelength at each site (col. 51, lines 1-5). Stoughton et al. disclose the relative abundance of mRNA is scored as a perturbation if there is a difference of the two sources of mRNA tested (col. 51, lines 14-27) which represents determining if the multidimensional coordinate point is within or outside the reference region and a difference (outside the region) is indication of linkage to a perturbation, as stated in instant claims 22, 24, and 30. Stoughton et al. disclose assigning a cellular function to components of a network or pathway (col. 10, line 58 to col. 11, line 3), as stated in instant claims 22, 24, and 30. Stoughton et al. disclose determining the overall goodness of fit of the network model (network-associated expression region) from the individual goodnesses of fit of

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each observed component (abstract), which also represents determining the multidimensional coordinate point representing a data element of a set of components in a network, as stated in instant claim 24. Stoughton et al. disclose observing a system's response to known inputs via gene expression and/or protein abundances (col. 2, first paragraph), as stated in instant claims 23, 26, 28, 29, 32, 34, and 35. Stoughton et al. disclose the biological system as a cell, organism, and patient (col. 5, line 67 to col. 6, line 1) which represents the biochemical system, as stated in instant claims 25 and 31.

Thus, Stoughton et al. anticipate the limitations in claims 22-35.

Applicants state the claimed invention is distinguishable from the Stoughton et al. reference, because Stoughton et al. do not describe determining a multidimensional coordinate point. This statement is found unpersuasive as several passages from Stoughton et al. represent such a point (i.e. col. 45, lines 17-39; col. 46, lines 58-67; col. 51, lines 39-49; and col. 52, lines 1-17). Applicants state a multidimensional coordinate point corresponds to a coordinate that is a combination of two or more data elements. It is noted that something that "corresponds to" something else, is not necessarily the original something itself. Applicants argue that Stoughton et al.'s measuring of transcription in response to graded drug exposure fails to describe determining a multidimensional coordinate point because such responses are directed to a type of dose-response measurements without integration of all values into a point as Applicants have described and claimed. This statement is found unpersuasive as the instant claims do not recite integration of all values into a point; but rather broadly mention a multidimensional coordinate point representing a data element that has been interpreted broadly and reasonably, as described

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in the rejection above. Applicants argue that Stoughton et al. do not combine multiple values into a multidimensional coordinate point. It is noted that such a limitation is not specifically stated in the instant claims, but rather only one interpretation of multidimensional coordinate point. Applicants refer to various excerpts of the specification regarding a multidimensional coordinate point; however, it is noted that the array interpretations of Stoughton et al. as set forth in the rejection above still encompass the instant claims due to broadly written claim language.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform to the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718.

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Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

December 5, 2005

A handwritten signature in black ink, appearing to read 'Carolyn Smith', with a stylized flourish at the end.

Carolyn Smith
Examiner
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